

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

Plaintiff CreAgri, Inc. (“CreAgri”) brings this action for patent infringement against Defendant PinnacLife Inc. (“PinnacLife”). The parties now seek construction of four disputed terms used in the claims of the following patents-in-suit: U.S. Patent Nos. 6,416,808 (“808 Patent”) and 8,216,599 (“599 Patent”). The Court held a technology tutorial and a claim construction hearing on February 8, 2013. The Court has reviewed the claims, specifications, and other relevant evidence, and has considered the briefing and arguments of the parties at the February 8, 2013 claim construction hearing. The Court now construes the terms at issue.

I. BACKGROUND

The two patents-in-suit generally relate to compounds obtained from olive plants. At the time of the invention, olives were known to contain compounds, that, when ingested, provide

beneficial health effects. *See* '808 Patent at 2:9-30. Those health effects were attributed to phenolic compounds, in particular, hydroxytyrosol and oleuropein. *See id.* Both hydroxytyrosol and oleuropein are present in the water byproduct obtained from industrial olive oil production, which is known as "vegetation water." *See* '808 Patent at 2:41-49. Tyrosol, another phenolic compound, also exists in vegetation water but is an undesired component. '808 Patent at 4:43-46.

The '808 Patent, entitled "Method of Obtaining a Hydroxytyrosol-rich Composition From Vegetation Water," is directed to olive-derived dietary supplements that contain hydroxytyrosol and oleuropein or hydroxytyrosol and tyrosol at certain weight ratios. *See* '808 Patent at 3:43-51. The patent specification also discloses methods for producing hydroxytyrosol-rich compositions from olives, which involves converting oleuropein present in the vegetation water to hydroxytyrosol under appropriate conditions. *See* '808 Patent at 2:57-67. However, no claim is directed towards these methods.¹ The '599 Patent, entitled "Method for Treatment of Inflammation," discloses methods for treating certain inflammation conditions, with a treatment agent containing substantially purified hydroxytyrosol or a substantially purified mixture of hydroxytyrosol and oleuropein. *See* '599 Patent Abstract.

CreAgri alleges that a number of Pinnaclife's products infringe the '808 Patent and the '599 Patent. ECF No. 50 ("Second Amended Complaint" or "SAC"), ¶¶ 51-77. In addition, CreAgri accuses Pinnaclife of actively inducing infringement of the '599 Patent. SAC, ¶ 60.

B. Claim Terms at Issue

In the parties' Joint Claim Construction Statement, the parties identified ten claim terms to be construed:

1. "comprising" or "comprised of";
2. "aqueous extract of olives";
3. "olive plant extract"

¹ The '808 Patent Application initially included 16 claims directed towards methods producing hydroxytyrosol-rich compositions from olives ("Method Claims"). *See* CreAgri's Opening Claim Construction Brief, Exs. 6 and 7. These claims were removed from the '808 Patent during prosecution pursuant to a restriction requirement. *See id.*, Ex. 7; Pinnaclife's Resp., Ex. D. Many of these claims (or claims similar to them) were ultimately included in a divisional of the '808 Patent, *see* U.S. Patent Nos. 7,261,909, and a continuation-in-part of the '808 Patent, *see* U.S. Patent No. 7,713,569.

4. “about”

5. “powder extract”

6. “inflammatory condition”

7. “clinical symptom” or “detectable clinical symptom”;

8. “marker” or “biochemical marker”;

9. “first treatment agent”

10. “second disease treatment agent” or “second treatment agent”

See ECF No. 43 (“Joint Claim Construction Statement”).

In the Joint Claim Construction Statement, the parties also identified two additional terms upon whose construction the parties agree.

Claim Language	Construction
“substantially purified” and “substantially purified mixture”	“a compound or compounds that are removed from their natural environment, isolated or separated, and are at least 60% free from other components with which they are naturally associated”
“coincident”	plain and ordinary meaning.

Id. at 1-2. The Court adopts the parties’ construction of these terms.

Additionally, in the course of claim construction briefing, CreAgri and PinnacLife agreed upon the construction of the following terms:

Claim Language	Construction
“about”	plain and ordinary meaning
“powder extract”	plain and ordinary meaning
“inflammatory condition”	plain and ordinary meaning
“first treatment agent”	plain and ordinary meaning
“olive plant extract”	“a preparation from an olive plant”
“second disease treatment agent” and “second treatment agent”	“a compound administered in addition to the first disease treatment agent of claim 1, where the compound acts to treat coronary, bronchial or neuro inflammation”

See PinnacLife’s Responsive Claim Construction Br. at 5-6 (“PinnacLife’s Resp.”) (adopting CreAgri’s proposed definitions of “about,” “powder extract,” “inflammatory condition,” “first

1 treatment agent,” and “olive plant extract”); CreAgri’s Reply Claim Construction Brief (“CreAgri’s
2 Reply”) at 15 (adopting PinnacLife’s definitions of “second disease treatment agent” and “second
3 treatment agent”). The Court adopts the parties’ construction of the aforementioned terms.

4 In PinnacLife’s Responsive Brief, PinnacLife states that, during the parties’ meet and confer
5 process, PinnacLife identified the following terms, which appear “in at least [C]laim 1 of the ‘599
6 [P]atent[,] as insolubly ambiguous and therefore indefinite: ‘normal range,’ ‘desired change,’
7 ‘elevated levels,’ and ‘respiratory distress.’” PinnacLife’s Resp. at 6. PinnacLife states that CreAgri
8 has offered no construction for these terms. *Id.* Accordingly, PinnacLife states that, if necessary,
9 PinnacLife will seek summary judgment of invalidity under 35 U.S.C. § 112 ¶ 2 consistent with the
10 Court’s scheduling order. *Id.* CreAgri responds that its position is, and has always been, that the
11 aforementioned terms require no construction because the plain and ordinary meaning applies. *See*
12 CreAgri’s Reply at 2. CreAgri notes that it stated as much in its preliminary claim construction
13 chart. *See* Declaration of Harold Storey in Support of Plaintiff CreAgri, Inc.’s Reply, ECF No. 52,
14 Ex. 1 at 5. Because the challenged terms were not identified as requiring construction in the
15 parties’ Joint Claim Construction Statement, and the parties have not briefed the issue of whether
16 these terms are insolubly ambiguous, the Court will not address them at this time.

17 Thus, the terms requiring construction by the Court are as follows:

- 18 1. “comprising” or “comprised of”;
- 19 2. “aqueous extract of olives”;
- 20 3. “clinical symptom” or “detectable clinical symptom”;
- 21 4. “marker” or “biochemical marker.”

22 Additionally, ostensibly in the context of construing the terms “comprising” or “comprised
23 of,” PinnacLife raised three additional construction issues:

- 24 1. whether the preamble “a dietary supplement” sets forth a limitation;
- 25 2. whether the weight ratios of hydroxytyrosol and oleuropein and hydroxytyrsol and
26 tyrosol described in Claims 1 and 5 of the ’808 Patent, respectively, apply to the
27 “dietary supplement” or to the “aqueous extract” referenced in those claims; and
28

3. whether the the weight ratio of hydroxytyrosol and oleuropein described in Claim 1 of the '599 Patent apply to the "first treatment agent" or "olive plant extract" referenced in that claim.

See Joint Claim Construction Statement at 3; PinnacLife's Resp. at 8-14.

While the Court does not agree with the parties that these construction issues are relevant to the proper construction of the terms "comprising" or "comprised of," the Court will address these issues as well.

II. LEGAL STANDARD

Claim construction is a question of law to be determined by the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd* 517 U.S. 370 (1996). "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). Accordingly, a claim should be construed in a manner that "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Id.*

In construing disputed terms, the court looks first to the claims themselves, for "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id.* at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Generally, the words of a claim should be given their "ordinary and customary meaning," which is "the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312-13. In some instances, the ordinary meaning to a person of skill in the art is clear, and claim construction may involve "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

In many cases, however, the meaning of a term to a person skilled in the art will not be readily apparent, and the court must look to other sources to determine the term's meaning. *Id.* Under these circumstances, the court should consider the context in which the term is used in an asserted claim or in related claims, bearing in mind that "the person of ordinary skill in the art is

1 deemed to read the claim term not only in the context of the particular claim in which the disputed
2 term appears, but in the context of the entire patent, including the specification.” *Id.* at 1313.
3 Indeed, the specification is “‘always highly relevant’” and “[u]sually [] dispositive; it is the single
4 best guide to the meaning of a disputed term.” *Id.* at 1315 (quoting *Vitronics Corp. v.*
5 *Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Where the specification reveals that the
6 patentee has given a special definition to a claim term that differs from the meaning it would
7 ordinarily possess, “the inventor’s lexicography governs.” *Id.* at 1316. Likewise, where the
8 specification reveals an intentional disclaimer or disavowal of claim scope by the inventor, the
9 inventor’s intention as revealed through the specification is dispositive. *Id.*

10 A court may also consider the patent’s prosecution history, which consists of the complete
11 record of proceedings before the United States Patent and Trademark Office (“U.S. PTO” or
12 “PTO”) and includes the cited prior art references. A court may consider prosecution history
13 where it is in evidence, for the prosecution history “can often inform the meaning of the claim
14 language by demonstrating how the inventor understood the invention and whether the inventor
15 limited the invention in the course of prosecution, making the claim scope narrower than it
16 otherwise would be.” *Id.* at 1317 (internal citations omitted).

17 Finally, a court is also authorized to consider extrinsic evidence in construing claims, such
18 as “expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980
19 (internal citations omitted). Expert testimony may be particularly useful in “[providing]
20 background on the technology at issue, [explaining] how an invention works, [ensuring] that the
21 court’s understanding of the technical aspects of the patent is consistent with that of a person of
22 skill in the art, or [establishing] that a particular term in the patent or the prior art has a particular
23 meaning in the pertinent field.” *Phillips*, 415 F.3d at 1318. Although a court may consider
24 evidence extrinsic to the patent and prosecution history, such evidence is considered “less
25 significant than the intrinsic record” and “less reliable than the patent and its prosecution history in
26 determining how to read claim terms.” *Id.* at 1317-18 (internal quotation marks and citation
27 omitted). Thus, while extrinsic evidence may be useful in claim construction, ultimately “it is
28 unlikely to result in a reliable interpretation of patent claim scope unless considered in the context

of the intrinsic evidence.” *Id.* at 1319. Any expert testimony “that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history” will be significantly discounted. *Id.* at 1318 (internal quotation marks and citation omitted).

III. DISCUSSION

A. “comprising” or “comprised of”

Terms in Dispute	CreAgri’s Proposed Construction	Pinnaclife’s Proposed Construction
“comprising” or “comprised of”	“including but not limited to”	<p>’808 Patent: “containing as part of the dietary supplement”</p> <p>’599 Patent: “containing as part of the treatment agent administered to a subject having an inflammatory condition”</p>

The term “comprising” appears in independent Claims 1 and 5 of the ’808 Patent, as follows:

1. A dietary supplement **comprising** an aqueous extract of olives containing a weight ratio of hydroxytyrosol to oleuropein of between about 5:1 and about 200:1.
5. A dietary supplement **comprising** an aqueous extract of olives containing a weight ratio of hydroxytyrosol and tyrosol of between about 3:1 and about 50:1.

’808 Patent at 10:36-38, 10:48-50 (emphasis added).

The term “comprised of” appears in Claim 1 of the ’599 Patent, as follows:

1. A method of treating a subject having an inflammatory condition characterized by a detectable clinical symptom or change in a level of a biochemical marker with respect to the normal range of the marker, the method comprising:
 - administering to the subject a dose corresponding to between about 0.1 mg/kg body weight and 2000 mg/kg body weight daily of a first treatment agent **comprised of** an olive plant extract having a weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1; and
 - continuing said administration until there is observed a return of the marker level to the normal range or a desired change in the clinical symptom, where the marker or the clinical symptom is selected from the group consisting of:
 - (i) elevated levels of C-reactive protein in the case of coronary inflammation;
 - (ii) respiratory distress in the case of bronchial inflammation; and

(iii) elevated CSF levels of isoprostanes or clinical symptoms determined from neuropsychological testing in the case of neuro inflammation.

'599 Patent at 19:37-20:5 (emphasis added).²

CreAgri argues that “comprising” and “comprised of” should be construed as permitting additional elements, and that, as a result, the terms should be construed as meaning “including but not limited to.” CreAgri’s Opening Claim Construction Brief (“CreAgri’s Opening Br.”) at 6. Notwithstanding the difference in the proposed language, PinnacLife does not dispute that the term “comprising... allows for incorporation of additional elements not expressly identified in the claim.” See PinnacLife’s Resp. at 7. Indeed, at the *Markman* hearing, both parties agreed to construe “comprising” and “comprised of” as “including but not limited to.” See ECF No. 62 (Transcript of the February 8, 2013 *Markman* Hearing) (“Tr.”) at 37:20-24, 38:16-20. This construction is consistent with how the Federal Circuit has construed these terms. See, e.g., *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) (“In the patent claim context the term ‘comprising’ is well understood to mean ‘including but not limited to.’” “The usual and generally consistent meaning of ‘comprised of,’ when it is used as a transition phrase, is, like ‘comprising,’ that the ensuing elements or steps are not limiting.”); see also Manual of Patent Examining Procedure (“MPEP”) § 2111.03 (“The transitional term ‘comprising’...is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.”). Accordingly, the Court adopts CreAgri’s construction and construes “comprising” and “comprised of” as “including but not limited to.”

PinnacLife raises two additional arguments in the context of construing “comprising” and “comprised of.” First, PinnacLife argues that the use of “dietary supplement” in the preambles of independent Claims 1 and 5 imposes a limitation on the ’808 Patent. See PinnacLife’s Resp. at 8. Second, PinnacLife argues that the weight ratios disclosed in Claims 1 and 5 of the ’808 Patent and

² In the Joint Claim Construction Statement, PinnacLife also proposed a construction for the term “comprising” as used in Claim 16 of the ’599 Patent. See ECF No. 43 at 3. This construction appears to have been abandoned in PinnacLife’s claim construction briefing. See PinnacLife’s Resp. at 6-7. At the *Markman* hearing, PinnacLife confirmed that it no longer disputes the meaning of “comprising” as used in Claim 16 of the ’599 Patent. See Tr. at 14:18-24. Accordingly, the Court only construes “comprising” or “comprised of” as used in Claims 1 and 5 of the ’808 Patent, and in Claim 1 of the ’599 Patent.

Claim 1 of the '599 Patent apply to the “dietary supplement” and “treatment agent” respectively. *See id.* at 12. The Court is not persuaded that these issues are related to the construction of “comprising” and “comprised of.” At the *Markman* hearing, PinnacLife agreed that the issues relating to the preamble and weight ratios did not necessarily need to be resolved in the context of construing “comprising” and “comprised of,” so long as these issues are addressed. *See* Tr. 102:21-103:21. Therefore, the Court addresses these two issues below in separate sections.

B. The Preamble “a dietary supplement”

Term in Dispute	CreAgri's Proposed Construction	PinnacLife's Proposed Construction
The preamble “a dietary supplement”	The preamble “a dietary supplement” is not a claim limitation.	The preamble “a dietary supplement” limits all claims of the '808 Patent.

“A dietary supplement” is used as preambles in independent Claims 1 and 5 of the '808 Patent, as follows:

1. **A dietary supplement** comprising an aqueous extract of olives containing a weight ratio of hydroxytyrosol to oleuropein of between about 5:1 and about 200:1.
5. **A dietary supplement** comprising an aqueous extract of olives containing a weight ratio of hydroxytyrosol and tyrosol of between about 3:1 and about 50:1.

'808 Patent at 10:36-38, 10:48-50 (emphasis added).

PinnacLife argues that the preamble “a dietary supplement” imposes a limitation on all claims of the '808 Patent. *See* PinnacLife's Resp. at 8. CreAgri, on the other hand, contends that “a dietary supplement” does not establish a limitation. *See* CreAgri's Reply Br. at 5-6.

As an initial matter, the Court notes with disapproval that PinnacLife did not raise its argument that the preamble is a claim limitation or disclose the evidence upon which it intended to rely in the Joint Claim Construction Statement. Nevertheless, the Court believes that CreAgri was able to adequately respond to PinnacLife's arguments in CreAgri's Reply and at the *Markman* hearing. Thus, the Court will address this issue on the merits.

In general, a preamble limits the invention if it recites essential structure or steps, or if it is “necessary to give life, meaning, and vitality” to the claim. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Conversely, a preamble is not limiting

“where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Id.* While there is no litmus test for determining when a preamble operates as a limitation, courts have provided certain “guideposts” or examples of circumstances in which a preamble may establish a claim limitation. These circumstances include when: (1) the “Jepson” form is used for a claim³; (2) the preamble is “essential to understand the limitations or terms in the claim body” (*e.g.* when a preamble phrase provides the antecedent basis for other terms in the claim body); (3) the preamble recites “additional structure or steps underscored as important by the specification”; and (4) a patentee clearly relies on the preamble during prosecution to distinguish the claimed invention from the prior art. *Id.*

Here, Pinnaclife makes several arguments regarding why the preamble “a dietary supplement” should be construed as limiting. First, citing *Catalina*, Pinnaclife argues that the preamble is limiting because it is “essential to understand the... terms in the... body” of dependent Claim 3. *See* Pinnaclife’s Resp. at 9 (quoting *Catalina*, 289 F.3d at 808). Pinnaclife also argues that its proposed construction is supported by the specification. *See id.* Finally, Pinnaclife makes several arguments relating to the prosecution history. *See id.* at 9-11. The Court will address the claim language, specification, and prosecution history in turn.

1. Claim Language

First, Pinnaclife argues that the preamble of independent Claims 1 and 5 should be construed as limiting because dependent Claim 3 “incorporates the preamble into” the body of Claim 3. *See id.* at 9. Dependent Claim 3 states: “The dietary supplement of [C]laim 1, wherein *said supplement* is dried to provide a powder extract.” ‘808 Patent at 10:42-43 (emphasis added). Pinnaclife argues that the reference to “supplement” in Claim 3 “may only be understood with reference to the ‘dietary supplement’ preamble.” *See id.* at 9. Thus, Pinnaclife argues that because

³ “A Jepson claim is to an improvement on an existing device, process[,] or combination, and includes (1) a preamble reciting conventional elements or steps, (2) a transition phrase such as ‘wherein the improvement comprises,’ and (3) the elements or steps the applicant considers to be new.” DONALD S. CHISUM ET AL., UNDERSTANDING INTELLECTUAL PROPERTY LAW 116 (2nd ed. 2011); *see also* 37 C.F.R. § 1.75(e). Here, neither Claim 1 nor Claim 5 claims an improvement on an existing device, process, or combination. Thus, neither claim is a Jepson claim.

1 the preamble is “essential to understand the limitations or terms in the body” of Claim 3, it is
2 limiting. *See id.* (quoting *Catalina*, 289 F.3d at 808). The Court is not persuaded by this argument.

3 *Catalina* did indeed recognize that a preamble may be limiting where the preamble
4 provides the antecedent basis for a term in the claim body, such that the preamble is “essential to
5 understand the limitations or term in the body.” *See Catalina*, 289 F.3d at 808. Applying this
6 principle, the *Catalina* Court found that the phrase “located at predesignated sites such as
7 consumer stores” limited independent Claim 25. *See id.* at 810-11. Claim 25 provided for: “A
8 system for controlling the selection and dispensing of product coupons at a plurality of remote
9 terminals *located at predesignated sites such as consumer stores*, comprising: a plurality of free
10 standing coupon display terminals *located at predesignated sites such as consumer stores*, each of
11 said terminals being adapted for bidirectional data communication with a host central processing
12 unit....” *Id.* at 806. The *Catalina* Court reasoned that because the phrase “located at predesignated
13 sites such as consumer stores” appeared in both “the preamble and [the] body of” that claim, the
14 preamble established a limitation. *See id.* at 810-11.

15 In the present case, the preamble “a dietary supplement” does not appear in the bodies of
16 Claims 1 and 5. Indeed, Claims 1 and 5 of the ’808 Patent “define[...]... structurally complete
17 invention[s].” *Id.* at 808. Specifically, Claims 1 and 5 describe compositions comprised of
18 aqueous extracts with certain ratios of hydroxytyrosol and oleuropein or hydroxytyrosol and
19 tyrosol, respectively. The preamble phrase “a dietary supplement” does not provide any additional
20 information about the structure of the compositions (*i.e.* its chemical components and their relative
21 ratios). Accordingly, removing the preamble phrase would “not affect the structure” of the claimed
22 compositions. *Id.* at 809 (“[T]he preamble generally is not limiting when the claim body describes
23 a structurally complete invention such that deletion of the preamble phrase does not affect the
24 structure or steps of the claimed invention.”). Thus, with respect to Claims 1 and 5, it appears that
25 “the preamble only... state[s] a purpose or intended use for the invention.” *Id.* at 808. As set forth
26 in *Catalina*, “preambles describing the use of an invention generally do not limit the claims
27 because the patentability of apparatus or composition claims depends on the claimed structure, not
28 on the use or purpose of that structure.” *Id.* at 809.

PinnacLife argues that the preamble “a dietary supplement” should, nevertheless, be construed as limiting because it appears in the preamble and the body of dependent Claim 3. *See* PinnacLife Resp. at 9. However, PinnacLife fails to cite, and the Court is unaware of, any authority for the proposition that a preamble phrase appearing in an independent claim should be construed as limiting that independent claim simply because that phrase appears in both the preamble and the body of a dependent claim. *Catalina* did not address this issue as the *Catalina* Court considered only whether the preamble found in independent Claim 25 was limiting where it appeared in both the preamble and the body of *that* claim. Thus, the Court is not persuaded that the preamble “a dietary supplement” should be construed as limiting Claims 1 and 5 (or the Patent as a whole) simply because it appears in the preamble and the body of dependent Claim 3. The claim language therefore does not support PinnacLife’s argument that the preamble is limiting. Furthermore, as well be discussed below, the specification confirms that compositions claimed in the ’808 Patent were not intended to be limited to uses as dietary supplements.⁴

2. Specification

PinnacLife also argues that several elements of the specification support PinnacLife’s construction that the preamble is limiting. *See* PinnacLife’s Resp. at 9. As explained in *Catalina*, a preamble may be limiting where it recites “additional structure or steps underscored as important by the specification.” *Catalina*, 289 F.3d at 808. Here, PinnacLife argues that “dietary supplement” should be construed as limiting because the Abstract states that: “The invention provides an olive-derived *dietary supplement* comprising hydroxytyrosol and oleuropein in specific weight ratios.” ’808 Patent Abstract. Similarly, the Summary of the Invention states that “the invention includes a dietary supplement.” *Id.* at 3:43-54. Finally, PinnacLife notes that the section

⁴ PinnacLife also argues that Dependent Claims 2 and 6 “do not stand as complete inventions without reading ‘supplement’ or ‘dietary supplement’ as part of the claim.” PinnacLife’s Resp. at 9. PinnacLife argues that this supports the conclusion that the preamble in Claim 1 is limiting. *See id.* Even accepting *arguendo* that Claims 2 and 6 did not “stand as complete inventions without reading ‘supplement’ or dietary supplement’ as part of the claim,” *id.*, PinnacLife fails to cite any authority for the proposition that a preamble phrase contained in an independent claim limits the independent claim if a dependent claim cannot “stand as a complete invention[]” without referencing the preamble phrase.

disclosing the composition is titled “Hydroxytyrosol-Rich *Dietary Supplement*.” *id.* at 7:28 (emphasis added).

The Court finds these references to the specification unpersuasive. None of the references “underscore[s]” that the dietary supplement use of the composition is an important part of the composition’s structure. *Catalina*, 289 F.3d at 808. The statement in the Abstract describes the composition as being “compris[ed] [of] hydroxytyrosol and oleuropein in specific weight ratios.” ’808 Patent Abstract. Like Claims 1 and 5 (discussed *supra*), the reference to a “dietary supplement” in the first portion of the Abstract sentence describes a possible use of the composition. *Id.* Similarly, the statement in the Summary of the Invention that “the invention includes a dietary supplement” does not clearly indicate that the composition’s use was meant to be limited to dietary supplements. *Id.* at 3:43-54 (emphasis).

Finally, and most significantly, the first sentence in the portion of the specification titled “Hydroxytyrosol-Rich Dietary Supplement” explicitly states that use as a dietary supplement is but one possible use for the invention: “III. Hydroxytyrosol-Rich Dietary Supplement. It should be appreciated that hydroxytyrosol produced by the method described above may be used for a *variety* of applications. For example...: (i) as a natural anti-bacterial, anti-viral and/or fungicidal product for agricultural and/or pest control applications, and (ii) as a therapeutic and/or an anti-oxidant for a variety of health purposes.” *See* ’808 Patent at 7:30-38 (emphasis added). Thus, rather than supporting PinnacLife’s construction, the specification supports CreAgri’s position that the invention is not limited to use as a dietary supplement. The Court next addresses PinnacLife’s arguments regarding the prosecution history.

3. Prosecution History

PinnacLife argues that the prosecution history supports its argument that the preamble should be limiting. Indeed, a preamble may be limiting where the inventor has “clear[ly] reli[ed] on the preamble during prosecution to distinguish the claimed invention from the prior art.” *Catalina*, 289 F.3d at 808. PinnacLife makes three arguments relating to the prosecution history. None of these arguments is persuasive. The Court addresses each argument in turn.

1 With respect to the prosecution history, PinnacLife first argues that in describing the
2 Reasons for Allowance, the Examiner stated: “WO 00/36936, is cited to show further the state of
3 the art with respect to *dietary supplement compositions* comprising aqueous extracts of tyrosol and
4 hydroxytyrosol.” Marshall Decl., Ex. E at 2 (emphasis added). PinnacLife argues that this
5 statement indicates that the Patent Examiner considered prior art relating to dietary supplements in
6 granting the ’808 Patent. PinnacLife’s Resp. at 11. The Court disagrees. While the Reasons for
7 Allowance indicate that the Patent Examiner considered other dietary supplements in granting the
8 ’808 Patent, in the same document, the examiner explicitly states that the ’808 Patent was granted
9 because it claimed unique mixtures of hydroxytyrosol to oleuropein or hydroxytyrosol to tyrosol.
10 See Marshall Decl., Ex. E (stating that the claim was allowed because “[n]one of the prior art
11 references teaches or suggests the weight ratios of hydroxytyrosol to oleuropein or hydroxytyrosol
12 to tyrosol as are instantly claimed”). Thus, the examiners’ Reasons for Allowance fail to
13 demonstrate that the dietary supplement use of the product was essential in distinguishing the
14 invention from the prior art such that it may be inferred that CreAgri “clear[ly] reli[ed]” on the
15 supplement’s dietary use in order to obtain its patent. *Catalina*, 289 F.3d at 808.

16 PinnacLife’s second prosecution history related argument concerns the patent Abstract.
17 PinnacLife notes that the portion of the Abstract reading “The invention provides olive-derived
18 hydroxytyrosol” was changed to “The invention provides *an* olive-derived *dietary supplement*
19 *comprising* hydroxytyrosol *and* oleuropein *in specific weight ratios*.” See Storey Decl., Ex. 7 at 18
20 (the emphasized terms represent the additions). Furthermore, the Abstract was revised to eliminate
21 certain language referring to certain non-dietary uses of the claimed invention including “as a
22 natural anti-bacterial, anti-viral[,] and fungicidal product.” *Id.*

23 These amendments to the Abstract fail to demonstrate the sort of clear reliance that would
24 warrant construing the preamble as limiting. PinnacLife has adduced no evidence suggesting that
25 the amendments were made to help distinguish the ’808 Patent from prior art. See *Textron*
26 *Innovations Inc. v. American Eurocopter Corp.*, No. 2011-1309, 2012 WL 3871717, at *29 (Fed.
27 Cir. Sept. 7, 2012) (holding that amendment to claim to add the term “replacement” did not limit
28 claim where “the amended application was silent as to why the term ‘replacement’ was added...

[and] [t]here was no express statement... that the term ‘replacement’ was added to overcome the rejection by limiting the invention to replacement parts only.”⁵ Accordingly, the Court finds that the amendments to the Abstract do not support the conclusion that the invention was intended to be limited to dietary supplement uses.

PinnacLife makes one final argument regarding the prosecution history. *See* PinnacLife’s Resp. at 10-11. PinnacLife notes that the original application for the ‘808 Patent included three different categories of claims. *See id.* The first two categories claimed: (1) a process of acidifying vegetation water to produce a hydroxytyrosol-rich composition (*see* Storey Decl., Ex. 7, Claims 1-9), and (2) a process of extracting a hydroxytyrosol-rich composition (*see id.*, Claims 10-16) (collectively with Claims 1-9, the “Method Claims”). The third category claimed a “dietary supplement” with a certain composition. *See id.*, Claims 17-22 (“Composition Claims”). The Method Claims were deleted from the ‘808 Patent during the course of prosecution leaving only the Composition Claims, which are Claims 1-6 in the final ‘808 Patent.⁶ PinnacLife argues that the inventor’s decision to use the term “dietary supplement” rather than the term “hydroxytyrosol-rich composition” in the Composition Claims was deliberate and “for reasons relating to the prior art” such that it may be inferred that the use of the term “dietary supplement” in the preambles was intended to be limiting. *See* PinnacLife’s Resp. at 11. The Court is not persuaded. PinnacLife provides no evidence or basis for its assertion that the term “dietary supplement” was used for reasons relating to the prior art. Consequently, this argument fails. Thus, the Court concludes that the patentee has not “clear[ly] reli[ed] on the preamble during prosecution to distinguish the claimed invention from the prior art.” *Id.*, 289 F.3d at 808.

For the reasons set forth above, the Court finds that the preambles “a dietary supplement” do not establish a limitation on the claim.

⁵ Moreover, the Court notes that when the Abstract was amended to eliminate the language relating to non-dietary uses, it was also amended to eliminate language describing certain dietary uses. *See* Storey Decl., Ex. 7 at 18 (striking “it is useful as a therapeutic and anti-oxidant for a variety of health purposes”).

⁶ As set forth *supra*, the Method Claims were removed from the ‘808 Patent during prosecution pursuant to a restriction requirement. PinnacLife’s Resp., Ex. D. Many of the Method Claims (or claims similar to the Method Claims) were incorporated into a separate patent, *see* U.S. Patent No. 7,261,909, and into a continuation of the ‘808 Patent, *see* U.S. Patent No. 7,713,569.

C. Weight Ratios Claimed in the '808 Patent

Term in Dispute	CreAgri's Proposed Construction	Pinnaclife's Proposed Construction
Weight ratios claimed in the '808 Patent	<p>In Claim 1 of the '808 Patent, the claimed weight ratio of hydroxytyrosol to oleuropein applies to the "aqueous extract of olives," not to the "dietary supplement."</p> <p>In Claim 5 of the '808 Patent, the claimed weight ratio of hydroxytyrosol to tyrosol applies to the "aqueous extract of olives," not to the "dietary supplement."</p>	<p>In Claim 1 of the '808 Patent, the claimed weight ratio of hydroxytyrosol to oleuropein applies to the "dietary supplement."</p> <p>In Claim 5 of the '808 Patent, the claimed weight ratio of hydroxytyrosol to tyrosol applies to the "dietary supplement."</p>

Claims 1 and 5 of the '808 Patent describe certain weight ratios of hydroxytyrosol to oleuropein and hydroxytyrosol to tyrosol, as follows:

1. A dietary supplement comprising an aqueous extract of olives containing a **weight ratio of hydroxytyrosol to oleuropein⁷ of between about 5:1 and about 200:1.**
5. A dietary supplement comprising an aqueous extract of olives containing a **weight ratio of hydroxytyrosol and tyrosol of between about 3:1 and about 50:1.**

'808 Patent at 10:36-38, 10:48-50 (emphasis added).

CreAgri argues that the weight ratios of the chemical compounds described in Claims 1 and 5 apply to the aqueous extract, but not to the dietary supplement. CreAgri's Opening Br. at 7-8. In other words, while the aqueous extract must contain the chemical compounds according to the claimed weight ratios, the dietary supplement need not. Pinnaclife, on the other hand, argues that

⁷ The Court notes that the claims in the '808 Patent refer to "oleuropein" whereas the claims in the '599 Patent refer to "oleuropein." See '808 Patent at 10:35-39; '599 Patent at 19:45. However, the definition for "oleuropein" in the '808 Patent indicates that it is the same chemical as the "oleuropein" referred to in the '599 Patent. See '808 Patent at 4:22-23 (defining "oleuropein" as "secoiridoid glucoside oleuropein (Structure II in FIG. 1)") (emphasis in original); '599 Patent at 5:15-16 (defining "oleuropein" as "secoiridoid glucoside oleuropein (Structure II in FIG. 1)") (emphasis in original); '808 Patent, Fig. 1, Structure II; '599 Patent, Fig. 1, Structure II. Moreover, the parties use "oleuropein" in their discussion of the '808 Patent. See e.g. CreAgri's Opening Claim Construction Brief at 2 ("The '808 Patent... is generally directed towards water-soluble dietary supplements that contain certain claimed ratios [sic] hydroxytyrosol to *oleuropein* or tyrosol.") (emphasis added); *id.* at 5, 7. Consequently, the Court uses the terms "oleuropein" and "oleuropein" interchangeably.

the weight ratios in Claims 1 and 5 should apply to the dietary supplement.⁸ PinnacLife's Resp. at 11-12.

As will be set forth below, the Court finds that CreAgri's construction is supported by the claim language, but that the specification and the prosecution history fail to affirmatively support either parties' construction. Below, the Court addresses the claim language, specification, and prosecution history in turn.

1. Claim Language

As an initial matter, the Court finds that the claim language supports CreAgri's proposed construction. In Claims 1 and 5, the restrictive phrases "containing a weight ratio," follow immediately after "aqueous extract of olives" (*see* '808 Patent at 10:36-38, 10:48-50), which suggests that the weight ratios apply to the "aqueous extract." If the weight ratios were intended to apply to the "dietary supplement," additional language could have been included to make this clear. For example, the claim language could have read "[a] dietary supplement comprising an aqueous extract of olives [*and*] containing a weight ratio." *See id.* Thus, the plain language of Claims 1 and 5 supports CreAgri's proposed construction wherein the weight ratios apply to the aqueous extract.

In PinnacLife's brief, PinnacLife argues that the language of dependent Claims 2 and 6, which depend on Claims 1 and 5 respectively, support the conclusion that the weight ratios described in Claims 1 and 5 apply to the dietary supplement. *See* PinnacLife's Resp. at 11-12. Claims 2 and 6 read:

2. The supplement of claim 1, which has a weight ratio of hydroxytyrosol to oleuropein of between about 10:1 and about 100:1.
6. The dietary supplement of claim 5, containing a weight ratio of hydroxytyrosol and tyrosol of between about 5:1 and about 30:1.

'808 Patent at 10:39-41; 10:51-54. PinnacLife argues that since Dependent Claims 2 and 6 serve to further limit the weight ratios of the chemical compounds contained in the dietary supplement, the

⁸ PinnacLife argues that, because the preambles are meant to serve as a limitation on Claims 1 and 5, "it is... clear that the dietary supplement must comprise the claimed weight ratios of" chemical compounds. PinnacLife's Resp. at 12. As set forth above, the Court has concluded that the preambles in Claims 1 and 5 were not meant to serve as a limitation on Claims 1 and 5. Furthermore, even if the preambles were meant to be limiting, it would not necessarily follow that the dietary supplement must be comprised of the claimed weight ratios.

weight ratios in Claims 1 and 5 must necessarily apply to the dietary supplement. *See* Pinnaclife's Resp. at 12. The Court disagrees.

As set forth above, Claim 1 claims:

A dietary supplement comprising an aqueous extract of olives containing a weight ratio of hydroxytyrosol to oleuropein of between about 5:1 and about 200:1.
'808 Patent at 10:36-38.

Claim 2 claims:

The supplement of claim 1, which has a weight ratio of hydroxytyrosol to oleuropein of between about 10:1 and about 100:1.

Id. at 10:39-41

The Court observes that because the dietary supplement described in Claim 1 is "compris[ed]" of the aqueous extract ('808 Patent at 10:36), the dietary supplement may have the same ratio of hydroxytyrosol and oleuropein as the aqueous extract. Thus, under CreAgri's proposed construction, wherein the ratio applies to the aqueous extract, Claim 1 would encompass dietary supplements "containing a weight ratio of hydroxytyrosol to oleuropein of between about 5:1 and about 200:1." *Id.* at 10:36-39. The dietary supplement claimed in Claim 2 has a narrower ratio (between 10:1 and 100:1) than the ratio described in Claim 1 (between 5:1 and 200:1). Thus, under CreAgri's construction wherein the ratio applies to the aqueous extract as opposed to the supplement, the dietary supplement in Claim 2 is still within the scope of Claim 1.

The same is true with respect to Claims 5 and 6. Claim 5 claims:

A dietary supplement comprising an aqueous extract of olives containing a weight ratio of hydroxytyrosol and tyrosol of between about 3:1 and about 50:1.

Id. at 10:48-50.

Claim 6 claims:

A dietary supplement comprising an aqueous extract of olives containing a weight ratio of hydroxytyrosol and tyrosol of between about 5:1 and about 30:1.

Id. at 10:51-54.

Because the dietary supplement described in Claim 5 is "compris[ed]" of the aqueous extract ('808 Patent at 10:36), the dietary supplement may have the same ratio of hydroxytyrosol and oleuropein as the aqueous extract. Thus, if the Court adopts CreAgri's construction wherein

the weight ratio described in Claim 5 applies to the aqueous extract, Claim 5 would encompass within its scope dietary supplements with a weight ratio of hydroxytyrosol and tyrosol of between about 3:1 and about 50:1. The ratio of the supplement described in Claim 6 is narrower (“between about 5:1 and 30:1”) (*see id.* at 10:52-54) than the ratio described in Claim 5. Thus, under CreAgri’s proposed construction, the supplement in Claim 6 would still be encompassed within the scope of Claim 5. Thus, PinnacLife’s argument fails.

Ultimately, given that the language of Claims 1 and 5 suggest that the weight ratios apply to the aqueous extract and that PinnacLife has failed to show that Claims 2 and 6 would be excluded by CreAgri’s proposed construction, the Court finds that the claim language supports CreAgri’s construction. Next, the Court examines the patent specification.

2. Specification

The patent specification does not affirmatively support either parties’ construction. On the one hand, the Abstract states: “The invention provides an olive-derived *dietary supplement* comprising hydroxytyrosol and oleuropein *in specific weight ratios*.” ’808 Patent Abstract (emphasis added); *see Hill-Rom Co., Inc. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1341 (Fed. Cir. 2000) (“[Courts] have frequently looked to the abstract to determine the scope of the invention...”) (citation omitted). Thus, the Abstract seems to support PinnacLife’s construction.⁹ On the other hand, in another part of the specification, the ’808 Patent explicitly discloses an aqueous extract containing hydroxytyrosol and oleuropein, or hydroxytyrosol and tyrosol, at the weight ratios described in Claims 1 and 5. *See* ’808 Patent at 7:50-56 (“[t]he aqueous...extracts can be formulated to contain various weight ratios of hydroxytyrosol to oleuropein of between 5:1 and 200:1... [or] hydroxytyrosol and tyrosol of between about 3:1 and about 50:1”). There is no similar disclosure about the dietary supplement. In light of this conflicting language, the specification fails to provide convincing support for either parties’ proposed construction.

⁹ However, the Court notes that the Abstract is silent about the weight ratio of hydroxytyrosol and tyrosol, the two ingredients in the composition claimed in Claim 5. Accordingly, the Abstract may not even be relevant to the question of whether the weight ratio in Claim 5 applies to the supplement or the aqueous extract.

3. Prosecution History

The prosecution history of the '808 Patent also fails to conclusively support either party's construction. The Notice of Allowability states that the '808 Patent was allowed because "[n]one of the prior art references teaches or suggests the weight ratios of hydroxytyrosol to oleuropein or hydroxytyrosol to tyrosol as are instantly claimed." *See* PinnacLife's Ex. E, ECF No. 49-6 at 3. Thus, the unique weight ratios claimed in the '808 Patent were essential in distinguishing it from the prior art. However, whether the examiner was talking about weight ratios of the chemical compounds as contained in the dietary supplement or, alternatively, in the aqueous extract is ambiguous. Other portions of the prosecution history likewise fail to clarify this point. Thus, the prosecution history fails to provide guidance as to whether the weight ratios apply to the supplement or the extract.

Because the language of Claims 1 and 5 supports CreAgri's construction, and the specification and prosecution history are ambiguous, the Court adopts CreAgri's construction that the claimed weight ratios in Claims 1 and 5 of the '808 Patent apply to the "aqueous extract of olives," not to the "dietary supplement." *See DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1347 (Fed. Cir. 2008) ("[A]bsent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis.").

D. Weight Ratio Claimed in the '599 Patent

Term in Dispute	CreAgri's Proposed Construction	PinnacLife's Proposed Construction
Weight ratios claimed in the '599 Patent	In Claim 1 of the '599 Patent, the claimed weight ratio of hydroxytyrosol to oleuropein applies to the "olive plant extract," not to the "first treatment agent."	In Claim 1 of the '599 patent, the claimed weight ratio of hydroxytyrosol to oleuropein applies to the "first treatment agent."

Claim 1 of the '599 Patent also describes a certain weight ratio of hydroxytyrosol to oleuropein. The relevant part of the claim language reads:

...administering to the subject a dose corresponding to between about 0.1 mg/kg body weight and 2000 mg/kg body weight daily of a first treatment agent comprised of an olive plant extract having a **weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1**; and...

1 '599 Patent at 19:41-46 (emphasis added).

2 PinnacLife argues that the weight ratio applies to the “first treatment agent.” *See*
3 PinnacLife’s Resp. at 13. PinnacLife argues that the claim language is ambiguous as to whether the
4 weight ratio applies to the “treatment agent” or to the “olive plant extract.” *Id.* PinnacLife contends
5 that it is, nevertheless, clear that the weight ratio applies to the treatment agent because the
6 specification “repeatedly [describes] the treatment agent, and not the olive plant extract, as having
7 the claimed weight ratio....” *Id.*

8 CreAgri argues that the weight ratio of hydroxytyrosol to oleuropein described in Claim 1
9 of the '599 Patent applies to the “olive plant extract.” *See* CreAgri’s Opening Br. at 8. CreAgri
10 argues that the claim language only requires that the olive plant extract have the claimed weight
11 ratio. *See id.* CreAgri also contends that PinnacLife’s argument that the weight ratio should be
12 construed as applying to the treatment agent because the weight ratio is described as applying to
13 the treatment agent in the specification is, in essence, an attempt to “limit[] the claimed
14 invention... [based on the] preferred embodiments... in the specification.” CreAgri’s Reply at 8.
15 (quoting *Verizon Services Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1302-03 (Fed. Cri.
16 2007)). For the reasons set forth below, the Court concludes that CreAgri’s construction is correct.

17 As an initial matter, the Court agrees with CreAgri that the claim language supports
18 CreAgri’s proposed construction. Similar to Claims 1 and 5 of the '808 Patent, the weight ratio in
19 Claim 1 of the '599 Patent immediately follows “olive plant extract.” *See* '599 Patent at 19:43-45
20 (“first treatment agent comprised of an olive plant extract having a weight ratio of....”). There is
21 no intervening language to suggest that the weight ratio was meant to apply to the first treatment
22 agent. For example, Claim 1 does not state “a first treatment agent comprised of an olive plant
23 extract [and] having a weight ratio of....” *Id.* Thus, the claim language is most consistent with
24 CreAgri’s proposed construction. Next, the Court considers the specification.

25 PinnacLife argues that its construction should be adopted in part because the specification
26 describes the weight ratio as applying to the treatment agent. *See* PinnacLife’s Resp. at 13. The
27 Court is not persuaded. The claimed weight ratio appears a total of four times in the specification.
28 On three of those occasions, the specification describes the weight ratio of hydroxytyrosol to

oleuropein as applying to “[the] treatment agent,” as opposed to “an olive extract.”¹⁰ Of these three instances, one is particularly supportive of PinnacLife’s construction. The language is as follows:

Summary of the Invention... In one embodiment, the weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1. In another embodiment, the weight ratio is between about 5:1 and about 100:1. In yet another embodiment, the weight ratio of hydroxytyrosol and oleuropein is between about 10:1 and about 50:1.

’599 Patent at 2:38-44. This example is noteworthy because the referenced weight ratios (1:1 and about 200:1, 5:1 and about 100:1, and 10:1 and about 50:1), correspond exactly to the weight ratios described in the claims. *See id.* at 19:43-46 (claiming as Claim 1 a “method comprising: administering... a first treatment agent comprised of an olive plant extract having a weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1”); *id.* at 20:6-7 (claiming as dependent Claim 2, “[t]he method of claim 1, wherein said weight ratio is between about 5:1 and about 100:1”); *id.* at 20:8-9 (claiming as dependent Claim 3, “[t]he method of claim 2, wherein said weight ratio is between about 10:1 and about 50:1”). The fact that the three embodiments in the specification that correspond so closely to Claims 1, 2, and 3 describe the weight ratios as applying to the treatment agent as opposed to the olive plant extract suggests that the weight ratio set forth in Claim 1 applies to the treatment agent.

Nevertheless, the Federal Circuit has cautioned that “though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim.” *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Thus, even if all the embodiments described in the specification include a certain limitation, the claims should not be construed as including this limitation unless the specification “expressly or by clear implication restrict[s] the scope of the invention.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 908 (Fed. Cir. 2004); *id.* at 906

¹⁰ *See* ’599 Patent at 7:56-58 (“In one aspect, the invention method comprises administering to a subject... an effective amount of *a treatment agent* having a weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1.”), 13:21-23 (“A dose of *an olive plant extract treatment agent* having a weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1...” (emphasis added)); *but see id.* at 3:15-18 (“The method includes administering to the subject a dose of an *olive plant extract treatment agent*. In one embodiment, *the extract* has a weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1”).

(“Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’”).

Here, as set forth above, the language of Claim 1 indicates that it is sufficient for the olive plant extract to have the claimed ratio of hydroxytyrosol to oleuropein. If the Court were to nevertheless construe the weight ratio as limiting the treatment agent because the embodiments in the specification limit the treatment agent, the Court would be improperly limiting the claim based on the specification. *See e.g. SuperGuide*, 358 F.3d at 875.¹¹ Accordingly, the Court declines to hold that the weight ratio applies to the treatment agent simply because the embodiments set forth in the specification apply weight ratios to the treatment agent.

Thus, the Court concludes that CreAgri’s construction, wherein the weight ratio applies to the “olive plant extract,” is correct.

E. “aqueous extract of olives”

Term in Dispute	CreAgri’s Proposed Construction	PinnacLife’s Proposed Construction
“aqueous extract of olives”	“a water-soluble preparation from an olive plant”	<p>“an aqueous solution containing water-soluble compounds obtained by washing and pressing olive fruit”</p> <p>As used in the ’808 Patent, “an aqueous extract” is not an “aqueous-alcoholic extract.” A powder is not an “aqueous extract.”</p>

The term “aqueous extract of olives” appears in Claims 1 and 5 of the ’808 Patent, as follows:

1. A dietary supplement comprising an **aqueous extract of olives** containing a weight ratio of hydroxytyrosol to oleuropein of between about 5:1 and about 200:1.

¹¹ The Court also notes that the embodiments in the specification -- *i.e.* those where the weight ratio applies to the treatment agent -- are not inconsistent with a construction of the claim in which the weight ratio applies to the olive plant extract. The olive plant extract is the source of hydroxytyrosol and oleuropein in the treatment agent. Thus, conceivably, the treatment agent may have the same ratio of hydroxytyrosol and oleuropein as the olive plant extract. Consequently, CreAgri’s construction, which construes the ratio of hydroxytyrosol and oleuropein as applying to the olive plant extract, does not exclude the embodiments described in the specification (*i.e.* those where the treatment agent contains the claimed ratio of hydroxytyrosol and oleuropein).

5. A dietary supplement comprising an **aqueous extract of olives** containing a weight ratio of hydroxytyrosol and tyrosol of between about 3:1 and about 50:1.

'808 Patent at 10:36-38, 10:48-50 (emphasis added).

While ostensibly seeking a construction of a single term “aqueous extract of olives,” the parties’ constructions raise three issues. First, the parties dispute whether “aqueous extract” must be a solution, or whether it may be a dry or powder extract which was derived using water. *See* Pinnaclife’s Resp. at 14 (arguing that the “aqueous extract” must be a solution); CreAgri’s Opening Br. at 10 (arguing that the “aqueous extract” may be a dry powder). Second, the parties dispute whether the “olive” component of the “aqueous extract” must be derived from the olive fruit, or whether it may be derived from any part of the olive plant. *See* Pinnaclife’s Resp. at 16 (arguing that the olive component must be obtained from the olive fruit); CreAgri’s Opening Br. at 12-13 (arguing that the olive component may be derived from any part of the olive plant). Finally, the parties dispute whether the “olive” component must be obtained by “washing and pressing.” *See* Pinnaclife’s Resp. at 16 (arguing that the olive component must be obtained by “washing and pressing”); CreAgri’s Opening Br. at 12 (arguing that the ’808 Patent does not limit the method by which the olive component is obtained). The Court addresses each of these issues in turn.

1. “Aqueous” Means a Solution

The parties’ dispute whether “aqueous extract” may be of a powdered form. Pinnaclife contends that the use of the term “aqueous” implies that the extract must be in a “watery” (*i.e.* liquid) form. Pinnaclife’s Resp. at 14. Pinnaclife argues that its construction is supported by the specification, which indicates that the aqueous extract is a solution. *See id.* at 15.

CreAgri argues that “aqueous extract” may refer to a powdered extract so long as it is derived from water. *See* CreAgri’s Opening Br. at 11. CreAgri contends that the word “aqueous” merely describes the origin of the compound, meaning that it was collected in water, rather than describing the current state of the compound. *See id.* at 9, 11. CreAgri argues that interpreting the term aqueous extract as requiring a watery or liquid substance would exclude dependent Claim 3. *See id.* at 11. At the *Markman* hearing, CreAgri also argued that dependent Claim 4 supports its construction. *See* Tr. at 108:1-6. Finally, CreAgri argues in its briefs that the extrinsic evidence,

specifically the dictionary definition of “aqueous,” supports CreAgri’s proposed construction. *See* CreAgri’s Opening Br. at 10.

The Court finds that Pinnaclife’s proposed construction is correct based on the specification. The Court is not persuaded by CreAgri’s arguments that CreAgri’s interpretation is necessary so as not to exclude Claim 3 or CreAgri’s argument that its interpretation must be adopted based on the extrinsic evidence. Below, the Court addresses: (1) Pinnaclife’s arguments regarding the specification; (2) CreAgri’s arguments regarding dependent Claims 3 and 4; and (3) CreAgri’s arguments regarding the extrinsic evidence.

a. Specification

As an initial matter, the Court agrees with Pinnaclife that its construction is the most consistent with the specification. *See In re Abbott Diabetes Care Inc.* (“*Abbott*”), 696 F.3d 1142, 1149 (Fed. Cir. 2012) (“Although the PTO emphasizes that it was required to give all claims their broadest reasonable construction, ... this court has instructed that any such construction be consistent with the specification.”); *see also Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1421 (Fed. Cir. 1988) (“[I]t is said the inventor may be his own lexicographer...But he must use his words consistently in the claims and in the specifications.”). The term “aqueous extract” appears three times in the specification.¹² In two of those instances, the specification merely recites the claim language. *See* ’808 Patent at 3:43-51. The third instance, however, is enlightening. It reads:

Oral dosage forms [of hydroxytyrosol] can be in solid or liquid form. Such dosage forms can be formulated from purified hydroxytyrosol or they can be formulated from *aqueous or aqueous-alcoholic extracts*. Regarding the latter, *aqueous or aqueous-alcoholic...extracts can be spray-dried to provide a dry powder* that can be formulated into oral dosage forms with other pharmaceutically acceptable carriers.

’808 Patent at 7:41-50 (emphasis added). The fact that the aqueous extract must be *dried* to

¹² Although not directly using the term “aqueous extract,” the Background of the Invention also states that “it is desirable to develop a method which produces an *aqueous olive extract* with a high percentage of hydroxytyrosol.” ’808 Patent at 2:52-54 (emphasis added). This statement, however, does not provide sufficient information to be of assistance in resolving the parties’ dispute.

1 provide a dry powder suggests the aqueous extract itself is not already in a dry form. *See id.*¹³

2 Notably, CreAgri appears to read the aforementioned statement regarding the spray-drying
3 of the aqueous extract into a dry power as an indication that the aqueous extract may be dry. *See*
4 CreAgri's Opening Br. at 10 (citing '808 Patent at 7:42-50). Indeed, the Court might agree with
5 CreAgri if the specification continued to refer to the extract as "aqueous extract" after the point of
6 spray-drying. However, the sentences following the spray-drying sentence address additional
7 characteristics of the aqueous extract and do not indicate whether the extract would continue to be
8 referred to as an "aqueous" extract after spray-drying.¹⁴

9 The Court also notes that, to the extent the specification uses adjectives to describe dry
10 forms of the extract, the specification uses the adjectives "dried" or "powder." For example, the
11 specification states that "the vegetation water of isolated hydroxytyrosol [may be used] to produce
12 a *dried* extract." '808 Patent at 3:10-11 (emphasis added). In another instance, the specification
13 states that: "The above supplements may be dried to provide a *powder* extract, which can [be]
14 formulated into a tablet, capsule, pill, or confection food additive." *Id.* at 3:52-54 (emphasis
15 added). These uses suggest that, where the inventor intended to refer to a dry extract, the inventor
16 referred to it using a term other than aqueous extract.

17 Thus, the Court finds that the specification supports PinnacLife's proposed construction
18 wherein the use of the term "aqueous" implies that the extract must be in a watery or liquid form.¹⁵

19
20 ¹³ Indeed, definitions of spray-drying expressly state that the substance being spray-dried must be a
21 fluid. *See* Perry's Chemical Engineers' Handbook, 7th Edition (1997) (defining spray-drying as
22 "[f]eed solids in a *fluid state* (solution, gel, paste, emulsion, slurry, or melt) are dispersed in a gas
23 and converted to granular solid products by heat.") (emphasis added); Hawley's Condensed
24 Chemical Dictionary, 13th Edition (1997) (defining "spray-dry" as "drying solids by spraying
25 *solutions of them* into a heated chamber.") (emphasis added).

26 ¹⁴ For example, the sentence in the specification following the spray-drying sentence provides that
27 the "aqueous extract" may be "formulated to contain various weight ratios of hydroxytyrosol to
28 oleoeuropein." '808 Patent at 7:50-53. It gives no indication as to whether an extract that has been
spray-dried would continue to be an "aqueous" extract.

¹⁵ At the *Markman* hearing, when asked what part of the specification supported its construction
that "aqueous extract" may be dry, CreAgri pointed to 8:28-34 of the '808 Patent. *See* Tr. 106:8-
10. It reads "[Parenteral formulations] are commonly prepared as sterile injectable solutions, using
a parenterally acceptable carrier such as isotonic saline solution or as a sterile packaged powder
prepared for reconstitution with sterile buffer or isotonic saline prior to administration to a
subject." While this paragraph appears to disclose a "powder," nowhere does it make clear that the
"aqueous extract" is the powder.

b. Dependent Claims 3 and 4

CreAgri argues that construing “aqueous extract” as a solution would exclude Dependent Claim 3. *See* CreAgri’s Opening Br. at 11. Claim 3 reads:

The supplement of claim 1, wherein said supplement *is dried* to provide a powder extract.

’808 Patent at 10:42-43 (emphasis added). Citing to the principle that a dependent claim must “include every limitation of the claim from which it depends...”, CreAgri contends that, if Claim 1 is construed as including a limitation pursuant to which the extract must be a liquid, Claim 3 will be excluded because it does not include this limitation, but instead permits a dry, “powder extract.” *See* CreAgri’s Opening Br. at 11 (quoting MPEP § 608.01). The Court is not persuaded.

Claim 3 does not indicate that the “aqueous extract” may be a dry powder. For example, Claim 3 does not state that “the supplement of claim 1, wherein said aqueous extract is a powder extract.” Instead, Claim 3 specifies that the dietary supplement in Claim 1 may be *dried*. This is entirely consistent with the interpretation that “aqueous extract” is a solution. Claim 3 simply implies that the supplement, which is comprised of an aqueous extract, may become a “powder extract” after undergoing a drying process.¹⁶ Claim 3 does not imply that the aqueous extract is dry in its original form. Claim 3 therefore does not omit the limitation that the aqueous extract is a liquid.¹⁷ Thus, construing Claim 1 as requiring a liquid extract would not exclude Claim 3.

At the *Markman* hearing, CreAgri argued, for the first time, that dependent Claim 4 also supports CreAgri’s proposed construction. *See* Tr. 108:1-6. Claim 4 recites, “The dietary supplement of claim 1, wherein said extract is in the form of a tablet, capsule, pill, or confection food additive.” ’808 Patent at 10:45-47. The only extract to which Claim 1 refers is the “aqueous extract.” It could be argued that because Claim 4 indicates that the extract may be in the form of a tablet, which is dry, then the aqueous extract may be dry, as opposed to a solution. The Court is

¹⁶ Notably, the language of Claim 3 states the “*supplement*” becomes a “powder *extract*” after being “dried.” ’808 Patent at 10:43-44 (emphasis added). There is no explanation as to why a *supplement*, which is comprised of an extract and potentially other ingredients, is referred to as an *extract* after it is dried. *See supra* Section III(B).

¹⁷ The Court further observes that in Claim 3 the inventor again uses a term other than “aqueous extract” to describe a dried version of the extract (i.e., “a powder extract”).

1 not persuaded that Claim 4 provides a sufficient basis to construe aqueous extract as including dry
2 powders.

3 Notably, the specification indicates that the extract must be processed before it can be
4 formed into a tablet, capsule, pill, or confection food additive. Specifically, the specification states
5 that, in order to be formed into a tablet, capsule, pill, and confection food additive form, a
6 “hydroxytyrosol-rich composition,” which may be in the form of an “extract,” must be “mixed,
7 diluted, or enclosed with a carrier.” *See id.* at 7:61-64. In some instances, the composition may
8 also be combined with additional elements including sugars, other flavoring agents, starches,
9 emulsifiers, and preservatives. *See id.* at 8:11-22. These statements imply that, in order to be
10 formed into a tablet, capsule, pill, and confection food additive form, the aqueous extract must be
11 mixed, diluted, or otherwise altered. Thus, in light of the specification, Claim 4’s statement that
12 the aqueous extract “is in the form of a tablet, capsule, pill, or confection food additive,” does not
13 necessarily support the conclusion that the aqueous extract was originally dry, but rather supports
14 the conclusion that the aqueous extract may be processed into a dry form. Because it appears from
15 the specification that the extract to which Claim 4 refers must be processed into a dry form, the
16 Court finds that Claim 4 does not support the conclusion that the aqueous extract may be dry.¹⁸

17 c. Extrinsic Evidence

18 The Court is also not persuaded by CreAgri’s extrinsic evidence. CreAgri argues that the
19 definition of “aqueous,” as set forth in the McGraw-Hill Dictionary of Scientific Terms, supports
20

21 ¹⁸ The Court is also reluctant to rely on Claim 4 because it is not clear that Claim 4’s statement that
22 the *extract* may be in the form of a tablet, capsule, pill, or confection food additive is accurate. The
23 specification suggests that it is the *supplement* rather than the aqueous extract that may be in the
24 form of a tablet, capsule, pill, or confection food additive. Specifically, the specification provides
25 that: “The above *supplements* may be dried to provide a powder extract, which can [be] formulated
26 into a tablet, capsule, pill, or confection food additive.” *Id.* at 3:52-54 (emphasis). However,
27 Claim 4 states that the “*extract* [may be] in the form of a tablet, capsule, pill, or confection food
28 additive.” ’808 Patent at 10:45-47. Given that the supplement is the final form of the product, it is
logical that it would be in an easily consumable form such as a tablet, capsule, pill, or confection
food additive. It is not necessarily clear that there would be a reason for the extract, which is a
mere component of the final product, to be processed into a tablet, capsule, pill, or confection food
additive. Consequently, the Court has concerns that, in stating that the *extract* may be in the form
of a tablet, capsule, pill, or confection food additive in Claim 4, the inventor may have incorrectly
substituted the term “extract” for “supplement.”

its construction. *See* CreAgri's Opening Br. at 10. The McGraw-Hill Dictionary of Scientific Terms defines "aqueous" as "[r]elating to or made with water." *See* Storey Decl., Ex. 4 (McGraw-Hill Dictionary of Scientific Terms, 4th Ex., 1989) at 114.¹⁹ CreAgri argues that it may be inferred from the aforementioned definition that "aqueous" only means that the extract must be extracted using water, not that it must still be in a liquid state. *See* CreAgri's Opening Br. at 10.

CreAgri's reliance on the dictionary definition is misplaced. As an initial matter, CreAgri's dictionary definition is from 1989, which is more than a decade before the 2001 effective filing date of the patent application. *See Phillips*, 415 F.3d at 1313 ("the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question *at the time of the invention, i.e., as of the effective filing date of the patent application.*") (emphasis added). Moreover, CreAgri's definition provides only limited support for CreAgri's position that the aqueous extract may be dry as the use of the phrase "relating to... water" is not necessarily broad enough to permit a watery solution that has been dried. Furthermore, even if the dictionary definition did support CreAgri's position, extrinsic evidence like the dictionary definition is "less significant than the intrinsic record." *See Phillips*, 415 F.3d at 1317 ("[W]hile extrinsic evidence can shed useful light on the relevant art,...it is less significant than the intrinsic record in determining the legally operative meaning of claim language" (internal quotations omitted)). Here, as discussed above, the only reference to the aqueous extract in the specification that gives any indication of its states indicates that it is a liquid, and, in several cases where the specification refers to a dried extract, it refers to it using the adjectives "dried" and "powdered." Thus, the intrinsic evidence in this case supports the conclusion that the use of the adjective "aqueous" in connection with the term "extract" implies that the extract is still in a liquid form.

Ultimately, given that the only reference to aqueous extract in the specification that gives any indication of the extract's state indicates that it is a liquid, the Court agrees with Pinnacliffe that

¹⁹ CreAgri further notes that "extract" is defined as "a preparation, usually in concentrated form, obtained by treating plant... tissue with a solvent to remove desired ... nutritive components." *Id.* at 684.

the term “aqueous extract” refers to a liquid extract, as opposed to merely referring to an extract that was originally obtained using water as a solvent. Thus, the Court construes the term “aqueous extract” as “an aqueous solution containing a water-soluble preparation.” Next, the Court addresses the parties’ dispute regarding whether the olive component of the aqueous extract must be obtained from the olive fruit or whether it may be obtained from any part of the olive plant.

2. “Olives” Do Not Refer Only to Olive Fruits

PinnacLife contends that, as used in the ’808 Patent, “olives” refer only to the olive fruits and that, accordingly, the “aqueous extract of olives” must be derived only from olive fruit. PinnacLife’s Resp. at 16-17. In support of this argument, PinnacLife notes that the ’808 Patent specification describes various methods for producing hydroxytyrosol-rich compositions. *See id.* at 16.²⁰ In describing these methods, the specification repeatedly references “olives” together with words that are characteristic of olive fruits such as “pits,” “pulp” and “olive meat.” *Id.* PinnacLife argues that these references support the conclusion that “olives” refer to olive fruit. *Id.*

CreAgri argues that “olives” refer to the entire olive plant and not just the fruits. CreAgri’s Opening Br. at 12. CreAgri argues that the claim language does not refer to olive *fruits*, and that the prosecution history also does not provide any indication that “the compositions had to be limited to extracts only from the olive fruit.” *Id.* CreAgri argues that, by attempting to construe olives as referring to only the olive fruit based on the references to olive meat and other portions of the olive fruit in the specification, PinnacLife is “inappropriately read[ing] a limitation from the written description into the claims.” *Id.* (citing *Phillips*, 415 F.3d at 1323). The Court agrees with CreAgri that the term “olives” should not be construed as referring exclusively to the olive fruit.

PinnacLife is correct that, in describing the methods for producing hydroxytyrosol-rich compositions, the patent specification repeatedly references “olives” together with words that are characteristic of olive fruits (*e.g.* “pits,” “pulp” and “olive meat”). *See, e.g.*, ’808 Patent at 2:31-32 (“[O]live oil production involves crushing *olives*, including the *pits*, to produce a thick paste.”),

²⁰ As set forth *supra*, the application for the ’808 Patent included a number of Method Claims, but these claims were deleted from the final version of the ’808 Patent. However, the descriptions of these methods in the specification remain.

4:43-44 (“*Pits* in the *olives* contain tyrosol which is an undesired component in the vegetation water...”), 4:53-55 (“To produce vegetation water, *olive pulp* from the *olives* is first pressed to obtain a liquid-phase mixture including olive oil...”), 5:1-3 (“Initially, *olives* are fed to a pulper that separates the *olive pits* from the *olives* to obtain a *pitless olive meat*.” (emphasis added)). However, this does not necessarily mean that the invention requires that the olive component be derived from olive fruit.

As set forth *supra*, the Federal Circuit has cautioned that, “[t]hough understanding... claim language may be aided by the explanations contained in the written description,” a court cannot “import into a claim limitations” from the written description. *SuperGuide*, 358 F.3d at 875. Thus, even if all the embodiments described in the common specification include a certain limitation, the claims should not be construed as including this limitation unless the specification “expressly or by clear implication restrict[s] the scope of the invention.” *Liebel-Flarsheim*, 358 F.3d at 908; *id.* at 906.

In this case, although the patentee repeatedly references the term “olives” together with words characteristic of olive fruits (*e.g.* “pits,” “pulp” and “olive meat”), nowhere in the specification does the patentee “expressly or by clear implication restrict” the term “olive” to olive fruits or reject the use of other components of the olive plant to obtain the claimed extract. *See Liebel-Flarsheim Co.*, 358 F.3d at 908. Indeed, the Field of the Invention indicates that any part of the olive plant may be used to the extent it states that “[t]his invention relates to a phenolic fraction of a group of compounds present in *olive plants* known as hydroxytyrosol...” ’808 Patent at 1:10-11. Accordingly, the Court declines to construe the term “olives” in Claims 1 and 5 of the ’808 Patent as being limited to “olive fruits.”

3. The Dietary Supplement Need Not Be Obtained Through “Washing and Pressing Olive Fruit”

PinnacLife next argues that the dietary supplement of the invention must be obtained through the process of “washing and pressing olive fruit.” PinnacLife’s Resp. at 17. CreAgri urges that no such limitation should be read into the claims. CreAgri’s Opening Br. at 12-13. The Court agrees with CreAgri.

The Federal Circuit has held that a true product claim, as opposed to a product-by-process claim, is not limited to the methods of manufacture disclosed in the specification. *Vanguard Products Corp. v. Parker Hannifan Corp.*, 234 F.3d 1370, 1372-73 (Fed. Cir. 2000) (“A novel product that meets the criteria of patentability is not limited to the process by which it was made.”); *Andersen Corp. v. Fiber Composites*, 474 F.3d 1361 (Fed. Cir. 2007) (“[T]he method of manufacture, even when cited as advantageous, does not itself convert product claims into claims limited to a particular process...”); *Compare Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570 (Fed. Cir. 1995) (process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention).

Here, Claims 1 and 5 of the ’808 Patent are product claims defined in terms of structural characteristics alone. Moreover, the prosecution history confirms that the patent was allowed because of the unique structural characteristics of the claimed product and not because of the method in which it is produced. *See* Pinnaclife’s Ex. E, ECF No. 49-6 at 3 (Notice of Allowability stating that the ’808 Patent was allowed because “[n]one of the prior art references teaches or suggests the weight ratios of hydroxytyrosol to oleuropein or hydroxytyrosol to tyrosol as are instantly claimed.”). Indeed, the patent examiner recognized that “the product may be prepared by more than one method,” and that “one could prepare the composition of [the invention] by merely physically mixing the known components of the composition.” *See* Office Action, ECF No. 47-7 at 4. Thus, the Court concludes that the dietary supplement of the invention need not be obtained through “washing and pressing olive fruit” as Pinnaclife proposes. *See Vanguard*, 234 F.3d at 1372-73.

Having addressed each of the parties’ disputes concerning the proper interpretation of the term “aqueous extract of olives,” the Court construes this term as “an aqueous solution containing a water-soluble preparation from an olive plant,” with no restriction on the process by which the “aqueous solution” is obtained.

F. “clinical symptom” or “detectable clinical symptom”

Terms in Dispute	CreAgri’s Proposed Construction	Pinnaclife’s Proposed Construction
“clinical	No construction necessary.	“subjective evidence of disease or

<p>1 symptom” or 2 “detectable 3 clinical symptom”</p>		<p>physical disturbance perceived by the patient and observed by a physician during clinical examination”</p> <p>“Clinical symptom” or “detectable clinical symptom,” as used in the ’599 Patent, refers only to (1) respiratory distress associated with bronchial inflammation or (2) clinical symptoms determined from neuropsychological testing where those symptoms are associated with neuro-inflammation, and excludes all other symptoms.</p>
--	--	--

7 The term “clinical symptom” and “detectable clinical symptom” both appear in Claim 1 of
8 the ’599 Patent, as follows:

- 9
- 10 1. A method of treating a subject having an inflammatory condition characterized
11 by a **detectable clinical symptom** or change in a level of a biochemical marker
12 with respect to the normal range of the marker, the method comprising:
- 13 administering to the subject a dose corresponding to between about 0.1
14 mg/kg body weight and 2000 mg/kg body weight daily of a first treatment
15 agent comprised of an olive plant extract having a weight ratio of
16 hydroxytyrosol to oleuropein of between about 1:1 and about 200:1; and
17 continuing said administration until there is observed a return of the marker
18 level to the normal range or a desired change in the **clinical symptom**,
19 where the marker or the **clinical symptom** is selected from the group
20 consisting of
- 21 (i) elevated levels of C-reactive protein in the case of coronary
22 inflammation;
 - 23 (ii) respiratory distress in the case of bronchial inflammation;
24 and
 - 25 (iii) elevated CSF levels of isoprostanes or clinical symptoms
26 determined from neuropsychological testing in the case of neuro
27 inflammation.

28 ’599 Patent at 19:37-20:5 (emphasis added).

CreAgri argues that “clinical symptom” is a plain, non-technical term that should be given its ordinary meaning. CreAgri’s Opening Br. at 20. PinnacLife argues that “clinical symptom” should be construed as requiring observation by both a patient and a physician. PinnacLife’s Resp. at 18. In addition, PinnacLife urges this Court to limit the scope of “clinical symptom” to only two conditions explicitly stated in Claim 1. *Id.* at 19-20. The Court addresses each of these arguments below.

1. “Clinical Symptom” Does Not Require the Observation of a Physician or a Patient

PinnacLife argues that the term “clinical symptom” should be construed as requiring that the symptom be observed by both a patient *and* a physician. *See* PinnacLife’s Resp. at 18-19. As stated by PinnacLife at the *Markman* hearing, PinnacLife’s primary purpose in pursuing this construction is to ensure that the jury understands that the symptom must be observed by a *physician* in addition to the patient. *See* Tr. at 74:16-23. PinnacLife argues that its construction is supported by the specification, extrinsic evidence (specifically, two dictionary definitions), and the statements of CreAgri’s counsel at the October 16, 2012 hearing on PinnacLife’s motion to compel. *See* PinnacLife’s Resp. at 18-19.

CreAgri argues that no construction of “clinical symptom” is necessary, and that PinnacLife’s construction is incorrect. *See* CreAgri’s Opening Br. at 20-21; CreAgri’s Reply at 12-13. In particular, CreAgri takes issue with PinnacLife’s proposed construction to the extent it requires observation by a physician. *See id.* CreAgri argues that PinnacLife’s proposed construction is not supported by the claim language or the specification, and that PinnacLife’s reliance on the dictionary definitions and CreAgri’s counsel’s statements at the October 16, 2012 hearing is misplaced. *See id.*

The Court agrees with CreAgri that the term “clinical symptom” should not be construed to require observation by both the patient and a physician. The Court addresses the parties’ arguments regarding: (1) the claim language; (2) the specification; (3) the extrinsic evidence; and (4) CreAgri’s counsel’s statements in turn.

With respect to the claim language, the Court observes that neither “physician,” “patient,” nor any similar terms appear in the claim language. *See* ’599 Patent at 19:37-20:5. Claim 1 merely states that “there *is observed*...a desired change in the clinical symptom,” without specifying who must observe the symptom. ’599 Patent at 19:47-49; *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1310 (Fed. Cir. 2005) (the court cautioned against including elements not mentioned in the claim in order to limit such claim) (citing *McCarty v. Lehigh Valley R. Co.*, 160 U.S. 110, 116 (1895)). Thus, the claim language does not support PinnacLife’s construction that the clinical symptom must be observed by the patient and a physician.

PinnacLife's construction also finds no support in the specification. The term "symptom" or "clinical symptom" appears eight times in the specification. The specification indicates that a "clinical symptom" is one that is "detectable" and observable. *See, e.g.*, '599 Patent at 3:13 ("a detectable clinical symptom"), 3:23-24 ("...until there is observed a return of the marker level to the normal range or a desired change in the clinical symptom."). However, like the claim language, the specification does not indicate whether a patient, a physician, or both must observe the clinical symptom. Indeed, the specification only makes a passing reference to "physician," and this reference does not suggest that a physician must observe the clinical symptom. *See* '599 Patent at 4-6 ("It will be understood that the amount of the compound actually administered will be determined by a physician..."). Similarly, while the word "patient" appears more often throughout the specification, it is generally associated with a certain type of disease. *See, e.g.*, '599 Patent at 9:15-16 ("...treating a patient suffering from peripheral neuropathy."). The specification does not give any indication that the "clinical symptom" must be observed by the patient and a physician.

PinnacLife's citations to extrinsic evidence are also unavailing. PinnacLife contends that its assertion that the symptom must be observed by both the patient and a physician is supported by two dictionary definitions of "clinical." PinnacLife's Resp. at 18. The first definition, which is from the 2002 edition of Webster's Third International Dictionary, defines "clinical" as "involving or depending on direct observation of the living patient; observable by clinical inspection." *See* Marshall Decl. ¶ 12, Ex. K (Webster's Third Int'l Dictionary). The second definition, which is from the 2006 edition of the American Heritage Dictionary, defines "clinical" as "involving or relating to direct observation of the patient." *See* Marshall Decl. ¶ 11, Ex. J (Am. Heritage Dictionary).

At the outset, the Court notes that the definition from the 2006 edition of the American Heritage Dictionary does not provide particularly probative evidence regarding the proper construction of the terms of the '599 Patent because this patent was filed three years earlier on Feb. 13, 2003.²¹ *See Phillips*, 415 F.3d at 1313 ("the ordinary and customary meaning of a claim term is

²¹ The Provisional Application of the '599 Patent was filed on Feb. 13, 2002.

1 the meaning that the term would have to a person of ordinary skill in the art in question *at the time*
2 *of the invention, i.e., as of the effective filing date of the patent application.*”) (emphasis added).
3 Moreover, while PinnacLife’s dictionary definitions define “clinical symptoms” as requiring “direct
4 observation,” neither definition requires observation by a “physician” as PinnacLife contends.
5 Furthermore, as a practical matter, in many instances, medical personnel other than a physician
6 may be charged with observing patients. Thus, contrary to PinnacLife’s assertion, the dictionary
7 definition does not support its construction.

8 Finally, PinnacLife directs the Court to a statement by CreAgri’s counsel that suggests a
9 doctor is required to observe the “clinical symptom.” *See* PinnacLife’s Resp. at 19. CreAgri’s
10 counsel made the statement during the hearing on PinnacLife’s motion to compel supplemental
11 infringement contentions, which reads:

12 Q: Is it your theory that the doctor will make [the determination that the
13 inflammation is gone] or is it that the customer takes the bill [sic] and is done?

14 A: I think when the doctor determines the inflammation is gone.

15 PinnacLife’s Resp. Ex. L, ECF No. 49-13 at 25:17-26:13. The Court is not persuaded. First,
16 PinnacLife points to no authority that instructs the Court to rely on counsel’s statement made during
17 a discovery hearing to interpret the meaning of a disputed claim term. *Cf. Phillips v. AWH Corp.*,
18 415 F.3d 1303, 1317 (Fed. Cir. 2005) (aside from intrinsic evidence, the court also authorizes
19 district courts to rely on evidence “external to the patent and prosecution history, including expert
20 and inventor testimony, dictionaries, and learned treatises.”) (citation omitted). Even if counsel’s
21 statement was proper evidence for claim construction, it cannot trump intrinsic evidence such as
22 the claim language and the specification. *See id.* (holding that “extrinsic evidence... is less
23 significant than the intrinsic record”) (internal quotations omitted). As explained above, the
24 intrinsic evidence imposes no limitation that a physician or a patient must observe the “clinical
25 symptom.” Thus, the Court declines to read this limitation into Claim 1 of the ’599 Patent.

26 For the reasons set forth above, the Court concludes that the term “clinical symptom” does
27 not imply that the symptom must be observed by both the patient and a physician.
28

2. “Clinical Symptom” Refers Only to the Two Symptoms Explicitly Disclosed in Claim 1

PinnacLife next argues that “clinical symptom” should be construed as referring to only those symptoms specifically identified in the claim. *See* PinnacLife’s Resp. at 19-20.

The relevant claim language reads “where the marker or clinical symptom is selected from the group *consisting of* (i) elevated levels of C-reactive protein in the case of coronary inflammation; (ii) respiratory distress in the case of bronchial inflammation; and (iii) elevated CSF levels of isoprostanes or clinical symptoms determined from neuropsychological testing in the case of neuro inflammation.” ’599 Patent at 19:50-20:5 (emphasis added). The parties agree that “respiratory distress in the case of bronchial inflammation” and “clinical symptoms determined from neuropsychological testing in the case of neuro inflammation” are “clinical symptom[s].” *See* Tr. 65:9-18; PinnacLife’s Resp. at 18. The parties also agree that: (1) “elevated levels of C-reactive protein in the case of coronary inflammation,” and (2) “elevated CSF levels of isoprostanes” are “marker[s].” *See* Tr. 65:9-18; PinnacLife’s Resp. at 18.

PinnacLife argues that the fact that the list of markers and symptoms is preceded by the term “consisting of” implies that the only two symptoms encompassed in the claim language are: (1) “respiratory distress in the case of bronchial inflammation,” and (2) “clinical symptoms determined from neuropsychological testing in the case of neuro inflammation.” *See* PinnacLife’s Resp. at 20. The Court agrees. In contrast to the term “comprising of,” the term “consisting of” is “well understood in patent usage... [to be] close-ended and convey limitation and exclusion.” *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1361 (Fed. Cir. 2007); *see also Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004) (“[C]onsisting of” is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim....”). Thus, the patent drafter’s use of the phrase “consisting of,” as opposed to “comprising of,” suggests that “clinical symptom” should be limited to the two symptoms explicitly stated in the claim.

At the *Markman* hearing, CreAgri generally agreed that “clinical symptom” should be limited to the symptoms explicitly stated in the claim. *See* Tr. at 117:9-12. However, CreAgri urged the Court to construe “clinical symptom” to include “coronary inflammation,” in addition to “respiratory distress...” and “clinical symptoms determined from neuropsychological testing...”

See id. at 118:18-119:15; '599 Patent at 19:53. The Court is not persuaded. The term “coronary inflammation” appears in the following claim language: “elevated levels of C-reactive protein *in the case of coronary inflammation.*” '599 Patent at 19:52-53 (emphasis added). As set forth *supra*, CreAgri has agreed this statement as a whole refers to a marker and not a symptom. Moreover, CreAgri fails to direct the Court’s attention to any intrinsic evidence supporting its assertion that “coronary inflammation” constitutes a separate clinical symptom. Thus, the Court declines to construe “clinical symptoms” as including “coronary inflammation.”²²

Thus, for the reasons stated above, “clinical symptom” or “detectable clinical symptom,” as used in the '599 Patent, refers only to (1) respiratory distress in the case of bronchial inflammation, or (2) clinical symptoms determined from neuropsychological testing where those symptoms are related to neuro-inflammation. The Court further clarifies that Claim 1 of the '599 Patent does not include the limitation that a physician or a patient must observe the “clinical symptom” or “detectable clinical symptom.”

G. “marker” or “biochemical marker”

Terms in Dispute	CreAgri’s Proposed Construction	PinnacLife’s Proposed Construction
“marker” or “biochemical marker”	No construction necessary.	<p>“a biological substance measured, detected, or observed by a physician to evaluate the presence of inflammation”</p> <p>“Marker” or “biological marker,” as used in the '599 patent, refers only to (1) C-reactive protein in the case of coronary inflammation or (2) CSF levels of isoprostanes in the case of neuro-inflammation, excludes all other biological substances.</p>

²² The Court notes that the specification does list one additional symptom: “joint pain and swelling in the case of joint inflammation,” *see* '599 Patent at 13:33-36. However, this symptom is not listed in the claim language. Moreover, at the *Markman* hearing, CreAgri conceded that the inventor had disavowed “joint pain and swelling” as a symptom. *See* Tr. at 68:20-64:6; Marshall Decl., Ex. H (“The Examiner’s attention is drawn to the fact that *the claims no longer recite symptoms such as those related to joint inflammation.* Thus, the Examiner’s remarks directed to this previously claimed aspect of the method are now rendered moot.”). Accordingly, the Court does not construe “clinical symptom” as including “joint pain and swelling in the case of joint inflammation.”

The terms “marker” and “biochemical marker” both appear in Claim 1 of the ’599 Patent, as follows:

1. A method of treating a subject having an inflammatory condition characterized by a detectable clinical symptom or change in a level of a **biochemical marker** with respect to the normal range of the **marker**, the method comprising:

administering to the subject a dose corresponding to between about 0.1 mg/kg body weight and 2000 mg/kg body weight daily of a first treatment agent comprised of an olive plant extract having a weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1; and

continuing said administration until there is observed a return of the **marker** level to the normal range or a desired change in the clinical symptom,

where the **marker** or the clinical symptom is selected from the group consisting of:

- (i) elevated levels of C-reactive protein in the case of coronary inflammation;
- (ii) respiratory distress in the case of bronchial inflammation; and
- (iii) elevated CSF levels of isoprostanes or clinical symptoms determined from neuropsychological testing in the case of neuro inflammation.

’599 Patent at 19:37-20:5 (emphasis added).

CreAgri argues that no construction is necessary. *See* CreAgri’s Opening Br. at 20. PinnacLife, on the other hand, argues that the term should be construed as meaning “a biological substance measured, detected, or observed by a physician to evaluate the presence of inflammation.” PinnacLife’s Resp. at 20-21. PinnacLife further argues that “marker” or “biochemical marker” refers only to the markers explicitly set forth in the claim. *See id.* at 20.

The Court disagrees with PinnacLife that a physician must measure, detect or observe the marker or biochemical marker. As set forth above in connection with the related term “clinical symptom,” the intrinsic evidence does not support including this additional limitation. Neither the claim language nor the specification requires that the marker be measured, detected or observed by a physician. CreAgri’s counsel’s statement that a physician must determine the presence or absence of inflammation, even assuming the statement is proper evidence for claim construction, cannot trump the intrinsic evidence. *See* PinnacLife’s Resp. Ex. L, ECF No. 49-13 at 25:17-26:13.

Thus, as with “clinical symptom,” there is no requirement that a physician must measure, detect or observe the marker or biochemical marker.

The Court does, however, agree with PinnacLife that “marker” or “biochemical marker” should be limited to the two markers expressly set forth in the claim language (“elevated levels of C-reactive protein in the case of coronary inflammation” and “elevated CSF levels of isoprostanes in the case of neuro-inflammation”). As noted above, the transition phrase “consisting of” is unambiguously close-ended, conveying limitation and exclusion. *See CIAS*, 504 F.3d at 1361.

Accordingly, the Court construes “marker” or “biochemical marker” as referring only to (1) elevated levels of C-reactive protein in the case of coronary inflammation or (2) elevated CSF levels of isoprostanes in the case of neuro-inflammation. *See* ’599 Patent at 19:50-20:5.²³ The Court further clarifies that Claim 1 of the ’599 Patent does not include the limitation that a physician must measure, detect or observe the marker or biochemical marker.

H. Conclusion

For the reasons discussed above, the Court construes the disputed claim terms as follows:

Claim Language	Construction
“comprising” or “comprised of”	“including but not limited to”
the preamble “a dietary supplement” in Claims 1 and 5 of the ’808 Patent	the preamble “a dietary supplement” in Claims 1 and 5 of the ’808 Patent is not a claim limitation.
weight ratios claimed in the ’808 Patent	the claimed weight ratios in Claims 1 and 5 of the ’808 Patent apply to the “aqueous extract of olives,” not to the “dietary supplement.”
weight ratio claimed in the ’599 Patent	the claimed weight ratio in Claim 1 of the ’599 Patent apply to the “olive plant extract.”
“aqueous extract of olives”	“an aqueous solution containing a water-soluble preparation from an olive plant,” with no restriction on the process by which the “aqueous solution” is obtained.

²³ In PinnacLife’s proposed construction for “markers,” neither “levels of C-Reactive protein...” nor “CSF levels of isoprostanes...” is preceded by the word “elevated.” Because the claim language includes the word “elevated” before both markers, *see e.g.* ’599 Patent at 19:52 (“elevated levels of C-reactive protein”), and the parties used the word “elevated” in connection with both markers at the *Markman* hearing, *see e.g.* Tr. at 65:9-14, the Court includes “elevated” in its final construction.

“clinical symptom” or “detectable clinical symptom”

“clinical symptom” or “detectable clinical symptom,” as used in the ’599 Patent, refers only to (1) respiratory distress in the case of bronchial inflammation, or (2) clinical symptoms determined from neuropsychological testing where those symptoms are related to neuro-inflammation.

Claim 1 of the ’599 Patent does not include the limitation that a physician or a patient must observe the “clinical symptom” or “detectable clinical symptom.”

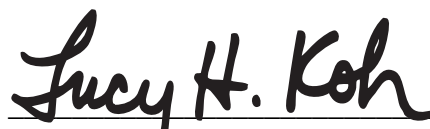
“marker” or “biochemical marker”

“marker” or “biochemical marker,” as used in the ’599 Patent, refers only to (1) elevated levels of C-reactive protein in the case of coronary inflammation or (2) elevated CSF levels of isoprostanes in the case of neuro-inflammation.

Claim 1 of the ’599 Patent does not include the limitation that a physician must measure, detect or observe the marker or biochemical marker.

IT IS SO ORDERED.

Dated: April 16, 2013



LUCY H. KOH
United States District Judge